



K132913
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GE Healthcare
510(k) Premarket Notification Submission

510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date: September 16, 2013

Submitter: GE Healthcare [GE Healthcare Austria GmbH & Co OG]
Tiefenbach 15
Zipf, Austria 4871

Primary Contact Person: Bryan Behn
Regulatory Affairs Manager
GE Healthcare
T:(414)721-4214
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NOV 08 2013

Secondary Contact Person: Roland Kuntscher
Regulatory Affairs Specialist
GE Healthcare Austria GmbH & Co OG
T:(++43)7682-3800-660
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Device: Trade Name: Voluson E Series

Models: Voluson E6/E8/E8Expert/E8Expert Limited Edition/
E10 Diagnostic Ultrasound Systems

Common/Usual Name: Voluson E6/E8/E8Expert/E8Expert Limited Edition/E10

Classification Names: Class II

Product Code: Ultrasonic Pulsed Doppler Imaging System. 21CFR 892.1550 90-IYN
Ultrasonic Pulsed Echo Imaging System. 21CFR 892.1560, 90-IYO
Diagnostic Ultrasound Transducer. 21 CFR 892.1570, 90-ITX

Predicate Device(s): K131267 Voluson E-Series E6/E8/E8Expert/E8Expert LE/E10
Diagnostic Ultrasound System

Device Description: The Voluson E-Series system is a full-featured Track 3 ultrasound system, primarily for general radiology use and specialized for OB/GYN with particular features for realtime 3D/4D acquisition. It consists of a mobile console with keyboard control panel; color LCD/TFT touch panel, color video display and optional image storage and printing devices. It provides high performance ultrasound imaging and analysis and has comprehensive networking and DICOM capability. It utilizes a variety of linear, curved linear, matrix phased array transducers including mechanical and electronic scanning transducers, which provide highly accurate realtime three dimensional imaging supporting all standard acquisition modes.



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Device Modification: This modification consists of a change to the labeling for the previously cleared SonoIT feature. Additionally, the previously cleared probe RAB4-8-D had been re-introduced to the Voluson E Series and a correction to the transducer application Obstetrics on the 9L-D have been made since the previous clearance.

Intended Use: The device is a general purpose ultrasound system. Specific clinical applications remain the same as previously cleared: Fetal/OB: Abdominal (including GYN, pelvic and infertility monitoring/follicle development); Pediatric: Small Organ (breast, testes, thyroid etc.); Neonatal and Adult Cephalic; Cardiac (adult and pediatric); Musculo-skeletal Conventional and Superficial; Peripheral Vascular; Transvaginal; Transrectal

Technology: The Voluson E-Series employs the same fundamental scientific technology as its predicate devices.

Determination of Substantial Equivalence: Summary of Non-Clinical Tests:

The device has been evaluated for acoustic output, biocompatibility, cleaning and disinfection effectiveness as well as thermal, electrical, electromagnetic, and mechanical safety, and has been found to conform with applicable medical device safety standards. The Voluson E-Series and its applications comply with voluntary standards:

1. IEC60601-1, Medical Electrical Equipment – Part 1: General Requirements for Safety
2. IEC60601-1-2, Medical Electrical Equipment – Part 1-2: General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility Requirements and Tests
3. IEC60601-2-37, Medical Electrical Equipment – Part 2-37: Particular Requirements for the Safety of Ultrasonic Medical Diagnostic and Monitoring Equipment
4. NEMA UD 3, Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment
5. ISO10993-1, Biological Evaluation of Medical Devices- Part 1: Evaluation and Testing- Third Edition
6. NEMA UD 2, Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment



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7. ISO14971. Application of risk management to medical devices
8. NEMA. Digital Imaging and Communications in Medicine (DICOM) Set. (Radiology)

The following quality assurance measures were applied to the development of the system:

- Risk Analysis
- Requirements Reviews
- Design Reviews
- Testing on unit level (Module verification)
- Integration testing (System verification)
- Final Acceptance Testing (Validation)
- Performance testing (Verification)
- Safety testing (Verification)

Transducer materials and other patient contact materials are biocompatible.

Summary of Clinical Tests:

The subject of this premarket submission, Voluson E Series, did not require clinical studies to support substantial equivalence.

Conclusion: GE Healthcare considers the Voluson E Series to be as safe, as effective, and performance is substantially equivalent to the predicate device(s).



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

November 8, 2013

GE HEALTHCARE
BRYAN BEHN
REGULATORY AFFAIRS MANAGER
9900 W INNOVATION DRIVE
WAUWATOSA WI 53226

Re: K132913

Trade/Device Name: Voluson E6 / E8 / E8expert / E8expert Limited Edition / E10
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed Doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, ITX
Dated: October 22, 2013
Received: October 24, 2013

Dear Mr. Behn:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

This determination of substantial equivalence applies to the following transducers intended for use with the Voluson E6 / E8 / E8expert / E8expert Limited Edition / E10 Diagnostic Ultrasound Systems, as described in your premarket notification:

Transducer Model Number

RAB2-5-D
RIC5-9-D
RNA5-9-D
4C-D
IC5-9-D
RSP6-16-D
RIC6-12-D
9L-D

P2D
P6D
11L-D
C1-5-D
ML6-15-D
RM6C
RRE5-10-D
RM14L

3Sp-D
C4-8-D
RAB6-D
eM6C
S4-10-D
RAB4-8-D

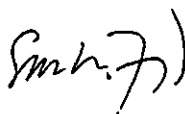
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



for

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure



GE Healthcare
510(k) Premarket Notification Submission

510(k) Number (if known): K132913

Device Name: Voluson E-Series (Voluson E6/E8/E8Expert/E8Expert Limited Edition/E10) Diagnostic Ultrasound Systems

Indications for Use:

The device is a general purpose ultrasound system. Specific clinical applications remain the same as previously cleared: Fetal/OB; Abdominal (including GYN, pelvic and infertility monitoring/follicle development); Pediatric: Small Organ (breast, testes, thyroid etc.); Neonatal and Adult Cephalic; Cardiac (adult and pediatric); Musculoskeletal Conventional and Superficial; Peripheral Vascular; Transvaginal; Transrectal

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use NA
(Part 21 CFR 801 Subpart C)

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IF NEEDED)

Concurrence of CDRL, Office of In Vitro Diagnostics and Radiological Health (OIR)



GE Healthcare

510(k) Premarket Notification Submission

Indications for Use Forms

The following forms represent indications with clinical applications and exam types along with the modes of operation for the Voluson E Series system and for all of its probe/mode combinations. Combinations identified as "P" represents those previously cleared with the unmodified Voluson E6/E8/E8Expert/E10 and "E" are those that have been added by Appendix E of the FDA Ultrasound guidance. This modification did not add to the previously cleared system level or transducer indications or clinical applications.



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Diagnostic Ultrasound Indications for Use Form

GE Voluson E-Series

(Voluson E6/E8/E8Expert/E8Expert Limited Edition/E10)

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics ^[1]	P	P	P	P	P	P	P	P	P	P	[5,6,9]
Abdominal ^[1]	P	P	P	P	P	P	P	P	P	P	[5,6,9]
Pediatric	P	P	P	P	P	P	P	P	P	P	[5,6,9]
Small Organ ^[2]	P	P	P	P	P	P	P	P	P	P	[5,6,9]
Neonatal Cephalic	P	P	P	P	P	P	P	P	P	P	[5]
Adult Cephalic	P	P	P	P	P	P	P	P	P	P	
Cardiac ^[3]	P	P	P	P	P	P	P	P	P	P	[5]
Peripheral Vascular	P	P	P	P	P	P	P	P	P	P	[5,6,9]
Musculo-skeletal Conventional	P	P	P		P	P	P	P	P	P	[5,6,9]
Musculo-skeletal Superficial	P	P	P		P	P	P	P	P	P	[5,6,9]
Other											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal ^[4]	P	P	P		P	P	P	P	P	P	[5,6,9]
Transvaginal	P	P	P		P	P	P	P	P	P	[5,6,9]
Transurethral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes renal, GYN/Pelvic.

[2] Small organ includes breast, testes, thyroid, salivary gland, lymph nodes, pediatric and neonatal patients

[3] Cardiac is Adult and Pediatric.

[5] 3D/4D Imaging Mode.

[6] Includes imaging of guidance of biopsy (2D/3D/4D).

[7] Includes infertility monitoring of follicle development.

[8] Includes urology/prostate.

[9] Elastography imaging- Elasticity

(*) Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

(†) 4D color Doppler

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)



GE Healthcare

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Diagnostic Ultrasound Indications for Use Form

GE Voluson E Series with RAB2-5-D Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other (Notes)
Ophthalmic											
Fetal / Obstetrics ^[1]	P	P	P	P	P	P	P	P	P	P	[5,6]
Abdominal ^[1]	P	P	P	P	P	P	P	P	P	P	[5,6]
Pediatric											
Small Organ ^[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac ^[3]											
Peripheral Vascular											
Musculo-skeletal Conventional	P	P	P	P	P	P	P	P	P	P	[5,6]
Musculo-skeletal Superficial											
Other											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes renal, GYN/Pelvic

[5] 3D/4D Imaging Mode

[6] Includes imaging of guidance of biopsy (3D/4D)

[7] Includes infertility monitoring of follicle development

[*] Combined modes are B/M, B/Color M, B/PW/D or CWD, B/Color/PW/D or CWD, B/Power/PW/D

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription User (Per 21 CFR 801.109)

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Diagnostic Ultrasound Indications for Use Form

GE Voluson E Series with RIC5-9-D Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomy Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics ^[1]	P	P	P		P	P	P	P	P	P	[5,6,9]
Abdominal ^[1]											
Pediatric											
Small Organ ^[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac ^[1]											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal ^[4]	P	P	P		P	P	P	P	P	P	[5,6,9]
Transvaginal	P	P	P		P	P	P	P	P	P	[5,6,9]
Transurethral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication, P = previously cleared by FDA, E = added under Appendix E

Notes [5] 3D/4D Imaging Mode

[6] Includes imaging of guidance of biopsy (3D/4D)

[7] Includes infertility monitoring of follicle development

[8] Includes urology/prostate

[9] Elastography Imaging- Elasticity

[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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Diagnostic Ultrasound Indications for Use Form

GE Voluson E Series with RNA5-9-D Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics ^[1]	P	P	P	P	P	P	P	P	P	P	[5,6]
Abdominal ^[1]	P	P	P	P	P	P	P	P	P	P	[5,6]
Pediatric	P	P	P	P	P	P	P	P	P	P	[5,6]
Small Organ ^[2]	P	P	P	P	P	P	P	P	P	P	[5,6]
Neonatal Cephalic	P	P	P	P	P	P	P	P	P	P	[5]
Adult Cephalic											
Cardiac ^[3]	P	P	P	P	P	P	P	P	P	P	[5]
Peripheral Vascular	P	P	P	P	P	P	P	P	P	P	[5,6]
Musculo-skeletal Conventional	P	P	P	P	P	P	P	P	P	P	[5,6]
Musculo-skeletal Superficial											
Other											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal ^[4]											
Transvaginal											
Transurethral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E.

- Notes:
- [1] Abdominal is Neonatal and pediatric
 - [2] Small organ includes breast, testes, thyroid, salivary gland, lymph nodes, pediatric and neonatal patients
 - [3] Cardiac is Neonatal and Pediatric
 - [5] 3D/4D Imaging Mode
 - [6] Includes imaging of guidance of biopsy (3D/4D)
 - [*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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Diagnostic Ultrasound Indications for Use Form

GE Voluson E Series with 4C-D Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other (Notes)
Ophthalmic											
Fetal / Obstetrics ^[7]	P	P	P	P	P	P	P	P	P	P	[6]
Abdominal ^[1]	P	P	P	P	P	P	P	P	P	P	[6]
Pediatric											
Small Organ ^[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac ^[3]											
Peripheral Vascular	P	P	P	P	P	P	P	P	P	P	[6]
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E.

Notes: [1] Abdominal includes renal, GYN/Pelvic, Urology

[6] Includes imaging of guidance of biopsy (2D)

[7] Includes infertility monitoring of follicle development

[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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Diagnostic Ultrasound Indications for Use Form

GE Voluson E Series with IC5-9-D Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomical Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics ^[1]	P	P	P		P	P	P	P	P	P	[6,9]
Abdominal ^[1]											
Pediatric											
Small Organ ^[1]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac ^[1]											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal ^[1]	P	P	P		P	P	P	P	P	P	[6,9]
Transvaginal	P	P	P		P	P	P	P	P	P	[6,9]
Transurethral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [6] Includes imaging of guidance of biopsy (2D)

[7] Includes infertility monitoring of follicle development

[8] Includes urology/prostate

[9] Elastography Imaging- Elasticity

[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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Diagnostic Ultrasound Indications for Use Form

GE Voluson E Series with RSP6-16-D Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other (Notes)
Ophthalmic											
Fetal / Obstetrics ^[2]											
Abdominal ^[1]											
Pediatric	P	P	P		P	P	P	P	P	P	[5,6]
Small Organ ^[2]	P	P	P		P	P	P	P	P	P	[5,6]
Neonatal Cephalic											
Adult Cephalic											
Cardiac ^[1]											
Peripheral Vascular	P	P	P		P	P	P	P	P	P	[5,6]
Musculo-skeletal Conventional	P	P	P		P	P	P	P	P	P	[5,6]
Musculo-skeletal Superficial	P	P	P		P	P	P	P	P	P	[5,6]
Other											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal ^[1]											
Transvaginal											
Transurethral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [2] Small organ includes breast, testes, thyroid, salivary gland, lymph nodes, pediatric and neonatal patients

[5] 3D/4D Imaging Mode

[6] Includes imaging of guidance of biopsy (3D/4D)

[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD

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Diagnostic Ultrasound Indications for Use Form

GE Voluson E Series with RIC6-12-D Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	(Other [Notes])
Ophthalmic											
Fetal / Obstetrics ^[7]	P	P	P		P	P	P	P	P	P	[5,6]
Abdominal ^[1]											
Pediatric											
Small Organ ^[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac ^[1]											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal ^[4]	P	P	P		P	P	P	P	P	P	[5,6]
Transvaginal	P	P	P		P	P	P	P	P	P	[5,6]
Transurethral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA. E = added under Appendix E.

Notes: [5] 3D/4D Imaging Mode

[6] Includes imaging of guidance of biopsy (3D/4D)

[7] Includes infertility monitoring of follicle development

[8] Includes urology/prostate

[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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Diagnostic Ultrasound Indications for Use Form

GE Voluson E Series with 9L-D Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other (Notes)
Ophthalmic											
Fetal / Obstetrics ⁽¹⁾	E	E	E	E	E	E	E	E	E	E	[6]
Abdominal ⁽¹⁾											
Pediatric	P	P	P	P	P	P	P	P	P	P	[6]
Small Organ ⁽²⁾	P	P	P	P	P	P	P	P	P	P	[6]
Neonatal Cephalic											
Adult Cephalic											
Cardiac ⁽⁴⁾											
Peripheral Vascular	P	P	P	P	P	P	P	P	P	P	[6]
Musculo-skeletal Conventional	P	P	P	P	P	P	P	P	P	P	[6]
Musculo-skeletal Superficial											
Other											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication, P = previously cleared by FDA, E = added under Appendix E

Notes: [2] Small organ includes breast, testes, thyroid, salivary gland, lymph nodes, pediatric and neonatal patients

[6] Includes imaging of guidance of biopsy (2D)

[7] Includes infertility monitoring of follicle development

[*] Combined modes are B/M, B/Color M, B/PWD or C/PWD, B/Color/PWD or C/PWD, B/Power/PWD

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Diagnostic Ultrasound Indications for Use Form

GE Voluson E Series with P2D Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other (Notes)
Ophthalmic											
Fetal / Obstetrics ^[1]											
Abdominal ^[1]											
Pediatric											
Small Organ ^[2]											
Neonatal Cephalic											
Adult Cephalic				P							
Cardiac ^[3]				P							
Peripheral Vascular				P							
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication, P = previously cleared by FDA; E = added under Appendix E

Notes: [3] Cardiac is adult and Pediatric

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GE Healthcare

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Diagnostic Ultrasound Indications for Use Form

GE Voluson E Series with P6D Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other (Notes)
Ophthalmic											
Fetal / Obstetrics ^[1]											
Abdominal ^[1]											
Pediatric											
Small Organ ^[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac ^[3]				P							
Peripheral Vascular				P							
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [3] Cardiac is adult and Pediatric

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Diagnostic Ultrasound Indications for Use Form

GE Voluson E Series with 11L-D Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other (Notes)
Ophthalmic											
Fetal / Obstetrics ^[2]											
Abdominal ^[1]											
Pediatric	P	P	P		P	P	P	P	P	P	[6.9]
Small Organ ^[2]	P	P	P		P	P	P	P	P	P	[6.9]
Neonatal Cephalic											
Adult Cephalic											
Cardiac ^[1]											
Peripheral Vascular	P	P	P		P	P	P	P	P	P	[6.9]
Musculo-skeletal Conventional	P	P	P		P	P	P	P	P	P	[6.9]
Musculo-skeletal Superficial	P	P	P		P	P	P	P	P	P	[6.9]
Other											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication, P = previously cleared by FDA, E = added under Appendix E

Notes: [2] Small organ includes breast, testes, thyroid, salivary gland, lymph nodes, pediatric and neonatal patients

[6] Includes imaging of guidance of biopsy (2D)

[9] Elastography Imaging- Elasticity

[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD

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Diagnostic Ultrasound Indications for Use Form

GE Voluson E Series with C1-5-D Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics ^[1]	P	P	P	P	P	P	P	P	P	P	[6]
Abdominal ^[1]	P	P	P	P	P	P	P	P	P	P	[6]
Pediatric											
Small Organ ^[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac ^[3]											
Peripheral Vascular	P	P	P	P	P	P	P	P	P	P	[6]
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes [1] Abdominal includes renal, GYN/Pelvic, Urology

[6] Includes imaging of guidance of biopsy (2D)

[7] Includes infertility monitoring of follicle development

[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD

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GE Voluson E Series with ML6-15-D Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other (Notes)
Ophthalmic											
Fetal / Obstetrics ^[1]											
Abdominal ^[1]											
Pediatric	P	P	P		P	P	P	P	P	P	[6,9]
Small Organ ^[2]	P	P	P		P	P	P	P	P	P	[6,9]
Neonatal Cephalic											
Adult Cephalic											
Cardiac ^[1]											
Peripheral Vascular	P	P	P		P	P	P	P	P	P	[6,9]
Musculo-skeletal Conventional	P	P	P		P	P	P	P	P	P	[6,9]
Musculo-skeletal Superficial	P	P	P		P	P	P	P	P	P	[6,9]
Other											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication, P = previously cleared by FDA, E = added under Appendix E

Notes: [2] Small organ includes breast, testes, thyroid, salivary gland, lymph nodes, pediatric and neonatal patients

[6] Includes imaging of guidance of biopsy (2D)

[9] Elastography Imaging-Elasticity

[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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Diagnostic Ultrasound Indications for Use Form

GE Voluson E Series with RM6C Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomical Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other (Notes)
Ophthalmic											
Fetal / Obstetrics ^[1]	P	P	P		P	P	P	P	P	P	[5,6]
Abdominal ^[1]	P	P	P		P	P	P	P	P	P	[5,6]
Pediatric	P	P	P		P	P	P	P	P	P	[5,6]
Small Organ ^[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac ^[3]											
Peripheral Vascular											
Musculo-skeletal Conventional	P	P	P		P	P	P	P	P	P	[5,6]
Musculo-skeletal Superficial											
Other											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication, P = previously cleared by FDA, E = added under Appendix E

Notes: [1] Abdominal includes renal, GYN/Pelvic, Urology

[5] 3D/4D Imaging Mode

[6] Includes imaging of guidance of biopsy (3D/4D)

[7] Includes infertility monitoring of follicle development

[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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Diagnostic Ultrasound Indications for Use Form

GE Voluson E Series with RRE5-10-D Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other (Notes)
Ophthalmic											
Fetal / Obstetrics ^[1]											
Abdominal ^[1]											
Pediatric											
Small Organ ^[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac ^[3]											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal ^[4]	P	P	P		P	P	P	P	P	P	[5,6,9]
Transvaginal	P	P	P		P	P	P	P	P	P	[5,6,9]
Transurethral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [5] 3D/4D Imaging Mode

[6] Includes imaging of guidance of biopsy (3D/4D)

[8] Includes urology/prostate

[9] Elastography Imaging- Elasticy

[*] Combined modes are B/M, B/Color M, B/PWID or CWD, B/Color/PWID or CWD, B/Power/PWID

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Diagnostic Ultrasound Indications for Use Form

GE Voluson E Series with RM14L Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomical Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other (Notes)
Ophthalmic											
Fetal / Obstetrics ^[2]											
Abdominal ^[1]											
Pediatric	P	P	P		P	P	P	P	P	P	[5,6]
Small Organ ^[2]	P	P	P		P	P	P	P	P	P	[5,6]
Neonatal Cephalic											
Adult Cephalic											
Cardiac ^[1]											
Peripheral Vascular	P	P	P		P	P	P	P	P	P	[5,6]
Musculo-skeletal Conventional	P	P	P		P	P	P	P	P	P	[5,6]
Musculo-skeletal Superficial	P	P	P		P	P	P	P	P	P	[5,6]
Other											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [2] Small organ includes breast, testes, thyroid, salivary gland, lymph nodes, pediatric and neonatal patients

[5] 3D/4D Imaging Mode

[6] Includes imaging of guidance of biopsy (3D/4D)

[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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Diagnostic Ultrasound Indications for Use Form

GE Voluson E Series with 3Sp-D Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other (Notes)
Ophthalmic											
Fetal / Obstetrics ^[1]	P	P	P	P	P	P	P	P	P	P	
Abdominal ^[1]	P	P	P	P	P	P	P	P	P	P	
Pediatric	P	P	P	P	P	P	P	P	P	P	
Small Organ ^[2]											
Neonatal Cephalic											
Adult Cephalic	P	P	P	P	P	P	P	P	P	P	
Cardiac ^[3]	P	P	P	P	P	P	P	P	P	P	
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication, P = previously cleared by FDA, E = added under Appendix E

Notes [1] Abdominal includes renal, GYN/Pelvic

[3] Cardiac is adult and Pediatric

[7] Includes infertility monitoring of follicle development

[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD

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Diagnostic Ultrasound Indications for Use Form

GE Voluson E Series with C4-8-D Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other (Notes)
Ophthalmic											
Fetal / Obstetrics ⁽¹⁾	P	P	P	P	P	P	P	P	P	P	[6]
Abdominal ⁽¹⁾	P	P	P	P	P	P	P	P	P	P	[6]
Pediatric	P	P	P	P	P	P	P	P	P	P	[6]
Small Organ ⁽²⁾											
Neonatal Cephalic											
Adult Cephalic											
Cardiac ⁽¹⁾											
Peripheral Vascular	P	P	P	P	P	P	P	P	P	P	[6]
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication, P = previously cleared by FDA, E = added under Appendix E

Notes: [1] Abdominal includes renal, GYN/Pelvic, Urology

[6] Includes imaging of guidance of biopsy (2D)

[7] Includes infertility monitoring of follicle development

[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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Diagnostic Ultrasound Indications for Use Form

GE Voluson E Series with RAB6-D Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics ^[1]	P	P	P	P	P	P	P	P	P	P	[5,6]
Abdominal ^[1]	P	P	P	P	P	P	P	P	P	P	[5,6]
Pediatric	P	P	P	P	P	P	P	P	P	P	[5,6]
Small Organ ^[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac ^[1]											
Peripheral Vascular											
Musculo-skeletal Conventional	P	P	P	P	P	P	P	P	P	P	[5,6]
Musculo-skeletal Superficial											
Other											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E.

Notes: [1] Abdominal includes renal, GYN/Pelvic, Urology

[5] 3D/4D Imaging Mode

[6] Includes imaging of guidance of biopsy (3D/4D)

[7] Includes infertility monitoring of follicle development

[*] Combined modes are B/M, B/Color M, B/PWID or CWD, B/Color/PWID or CWD, B/Power/PWID.

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Diagnostic Ultrasound Indications for Use Form

GE Voluson E Series with eM6C Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color* Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics ^[1]	P	P	P		P	P	P	P	P	P	[5,6]
Abdominal ^[2]	P	P	P		P	P	P	P	P	P	[5,6]
Pediatric	P	P	P		P	P	P	P	P	P	[5,6]
Small Organ ^[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac ^[3]											
Peripheral Vascular											
Musculo-skeletal Conventional	P	P	P		P	P	P	P	P	P	[5,6]
Musculo-skeletal Superficial											
Other											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication, P = previously cleared by FDA, E = added under Appendix E

Notes [1] Abdominal includes renal, GYN/Pelvic, Urology

[5] 3D/4D Imaging Mode

[6] Includes imaging of guidance of biopsy (3D/4D)

[7] Includes infertility monitoring of follicle development

[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD

[] 4D color Doppler

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Diagnostic Ultrasound Indications for Use Form

GE Voluson E Series with S4-10-D Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other (Notes)
Ophthalmic											
Fetal / Obstetrics ^[1]	P	P	P	P	P	P	P	P	P	P	
Abdominal ^[1]	P	P	P	P	P	P	P	P	P	P	
Pediatric	P	P	P	P	P	P	P	P	P	P	
Small Organ ^[2]	P	P	P	P	P	P	P	P	P	P	
Neonatal Cephalic	P	P	P	P	P	P	P	P	P	P	
Adult Cephalic											
Cardiac ^[3]	P	P	P	P	P	P	P	P	P	P	
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other ^[4]											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal ^[5]											
Transvaginal											
Transurethral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA;

Notes:

[1] Abdominal includes renal, GYN/Pelvic, Urology

[2] Small organ includes breast, testes, thyroid, salivary gland, lymph nodes, pediatric and neonatal patients

[3] Cardiac is Adult and Pediatric

[4] Includes infertility monitoring of follicle development

[5] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD

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Diagnostic Ultrasound Indications for Use Form

GE Voluson E Series with RAB4-8-D Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other (Notes)
Ophthalmic											
Fetal / Obstetrics ^[7]	E	E	E		E	E	E	E	E	E	[5,6]
Abdominal ^[1]	E	E	E		E	E	E	E	E	E	[5,6]
Pediatric	E	E	E		E	E	E	E	E	E	[5,6]
Small Organ ^[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac ^[1]											
Peripheral Vascular											
Musculo-skeletal Conventional	E	E	E		E	E	E	E	E	E	[5,6]
Musculo-skeletal Superficial											
Other											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E (Previously cleared K122327)

Notes: [1] Abdominal includes renal, GYN/Pelvic

[5] 3D/4D Imaging Mode

[6] Includes imaging of guidance of biopsy (3D/4D)

[7] Includes infertility monitoring of follicle development

[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription User (Per 21 CFR 801.109)

(Signature)

(Division Sign-Off)

Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

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